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| 10/757,433 | 01/15/2004 | Horst Ulbricht | 02481.1790-01 | 4111 |
| 22852 | 7590 | 12/16/2005 | EXAMINER | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | FUBARA, BLESSING M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1618 | |

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/757,433

Applicant(s)

ULBRICHT ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8-14,17,19,21,22,24-35,38-42 and 44 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 1,3-6,8-14,17,19,21,22,24-35,38-42 and 44 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 09/20/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, IDS, amendment and remarks filed 09/20/05. Claims 1, 3-6, 8-14, 17, 19, 21, 22, 24-35, 38-42 and 44 are pending.

Response to Amendment

1. The amendment filed 09/20/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure is as follows: Deletion or removal of “one or more” from paragraphs 10 and 22 of the specification introduces new matter to the disclosure. The specification as originally filed does not support deleting/removing “one or more” that identifies the extent of the nonvolatile constituents. The specification as originally filed does not state that the nonvolatile constituents are urea and hydrophilic polymer; specifically, paragraph 23 states “the amounts of urea are in each case based on the **nonvolatile constituents** of the use according to the invention and can be from 35 to 85 percent by weight, from 39 percent by weight to 83 percent by weight, from 46 percent by weight to 63 percent by weight, or from 55 percent by weight to 63 percent by weight.”

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

2. The rejection of claims 1, 3-6, 9-11, 17, 19, 21, 22, 24, 26-29, 31, 35, 38, 39 and 42 under 35 U.S.C. 102(b) as being anticipated by GB 2 202 743 is withdrawn because the amendment to the claims now require the urea to be the only active agent and the GB reference has econazole or miconazole as antifungal agents.

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Therefore, applicants' arguments with respect to the GB reference are moot.

3. The rejection of claims 1, 8, 17, 24, 25, 28-35, 40-42 and 44 under 35 U.S.C. 102(e) as being anticipated by Kraemer et al. (US 2003/0012749) is withdrawn in light of the amendment, which now recites the amount of urea to be from 41 percent by weight to 69 percent by weight and while the amount of urea in Kraemer is from about 70-90 with a preferred amount of 75-85 percent by weight of the non-volatile components. However, there is no demonstration in applicants' specification or in the remarks showing that the recited amount of 69% provides unexpected result over the 70 % or 39% or 40%. Kraemer renders the claims obvious and therefore, the amendment necessitates an obviousness rejection of claims 1, 8, 17, 24, 25, 28-35, 40-42 and 44.

Claim Rejections - 35 USC § 103

4. Claims 3-6, 12-14, 19, 21, 22, 26, 27, 38 and 39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kraemer et al. (US 2002/0012749 A1). Claims 1, 8, 17, 24, 25, 28-35, 40-42 and 44 are included in this rejection and this inclusion is necessitated by the amendment.

Kraemer discloses cosmetic or pharmaceutical composition that comprises urea, film forming hydrophilic polymer and water (abstract, paragraph (00131 and Examples 1-6). The composition may also contain customary cosmetic additives such as plasticizers (paragraph (0019). Kraemer discloses that the urea is present in amounts of from 70-90% by weight of the non-volatile constituents and the hydrophilic film former is present in amounts of between 10 and 30% (abstract; paragraph [0015]. A water/alcohol mixture may also be used (paragraph

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(00221). Kraemer's composition does not contain urea in amounts of less than about 70% since Kraemer's lower limit of 70% for the urea is higher than the upper limit of 69% for urea of the instant claims. However, generally, differences in amounts of urea will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount provides unexpected/unusual results. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the cosmetic composition of Kraemer. One having ordinary skill in the art would have been motivated to prepare the cosmetic formulation of Kraemer and use urea in amounts that would be expected to effectively remove diseased keratin from areas such as toenails and fingernails.

Applicants' arguments with respect to Kraemer:

Applicants state that the 70% or 75% of urea in Kraemer do not overlap the 41-69% urea now recited by the claims, that the preferred amount of 75-85% urea in Kraemer leads away from the 41-69% urea now recited by the amendment, and that the examples of Kraemer all disclose amounts of urea that is greater than 70%. Thus applicants conclude that, Kraemer "fails to guide the person skilled in the art in the direction of making the invention now claimed."

5. Applicants' arguments filed 09/20/05 have been fully considered but they are not persuasive.

The difference between Kraemer and the instant claims is in the amounts of urea. However, applicants have provided no demonstration with factual evidence outside the limits of

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the claimed urea range that the amounts of urea recited provide unusual and unexpected results to the claimed invention over the prior art. And generally, differences in amounts of urea will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount provides unexpected/unusual results. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

6. Claims 1, 3-6, 8-14, 17, 19, 21, 22, 24-35, 38-42 and 44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 5,874,074).

Applicants argue that because Smith discloses an emulsion, the claimed invention, which is claimed as a solution, is patentably distinct from Smith's lotion, which is an emulsion; that the reference in applicants' specification to suspending urea is one of the embodiments described in the specification; that the treatment of skin disorders in Smith does not lead to treating toenails or fingernails a clarification is requested since skin and nails are different; and Smith does not disclose the claimed amounts of urea.

7. Applicants' arguments filed 09/20/05 have been fully considered but they are not persuasive.

Regarding the amount of urea used in the claimed invention and the prior art it is noted that applicants have not presented factual evidence showing unexpected/unusual results provided by the claimed amount of the urea over the urea containing composition of the prior art.

Regarding toe nails and finger nails in the method claims 30, it is noted that the method contacts the abnormal keratin with the composition and since the keratinous material is of the skin and

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Smith applies the composition to the skin, it is obvious that application of the composition of Smith to the skin does not exclude application of the composition to the nails of the toes. Smith encompasses the instant method and toe and fingers have skin areas. The skin disorders referenced by Smith are psoriasis, eczema atopic dermatitis, alopecia areata, warts, keratoses (overgrowth of honey tissue) and acne. Regarding lotion vs. solution, it is observed that lotion and solution are carriers.

8. In response to applicants' argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicants' disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

9. In response to applicant's argument that there is no suggestion to modify the reference, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Specifically, Smith prepares the phases separately and the urea and the film-forming polymer are present in the aqueous phase as a solution and the aqueous phase is not miscible

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with the oil phase and the composition of Smith contains about 70% water. Smith prepares the oil phase separately from the water phase and the urea and the PVP are soluble in water and are therefore in solution in the water phase.

The rejection below applies.

Smith discloses a composition comprising polyvinylpyrrolidone in amounts of 0.5-15 weight (column 4, line 17, column 5, line 25 and claims 1 and 14), urea (column 5, line 7), water and anti-microbial agents in amounts 0.025-1-weight% (column 6, line 6). The composition of Smith is prepared as a lotion and applied to skin to treat pathologies of the skin (column 7, lines 43-48), and warts, corns (hard skin), and Zook (US 5,098,421), a teaching reference discloses at column 7, lines 7 and 8 that keratolytic agents such as salicylic acid, lactic acid, or urea could be used to treat corns or calluses. Specifically, Smith discloses salicylic acid and lactic acid as wart removing agents (column 5, line 10) and lists salicylic acid and urea as keratolytic. Thus, urea as keratolytic agent has activity against calluses and hard skin or corn and even warts (see claim 17 and Zook). Generic claim 17 is directed to treating one of the conditions of wart, calluses and hard skin or corn. Regarding the amount of the polyvinylpyrrolidone, it is within the purview of the person of ordinary skill in the art to optimize the lotion of Smith by including appropriate amount of polyvinylpyrrolidone to enhance the penetration of urea and to serve as occlusive film barrier.

Smith prepares the oil phase separately from the water phase and the urea and the PVP are soluble in water and are therefore in solution in the water phase.

Smith discloses a composition for treating pathologies of the skin, which includes calluses and corn (hard skin). Regarding toenails and fingernails, it is obvious that the

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composition of Smith applied to the skin also gets on the nails of the toes and fingers. Smith fails to disclose amounts of urea and failure to specifically disclose an amount of urea reflects that the amount of urea may be added to the composition as needed. However, amounts will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such amount is critical. The comprising language of the claims is open.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and apply to the skin the lotion of Smith to treat pathologies of the skin such as calluses, hard skin or corn and warts. One having ordinary skill in the art would have been motivated to include an effective amount of urea with the expectation that application of the modified or optimized lotion of Smith to the skin would treat pathologies of the skin such as calluses, hard skin or corn and warts.

Double Patenting

Claims 17, 19, 21, 22, 24 and 26-29 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17-24 and 26-29 of copending Application No. 10/156,070.

Applicants state that the withdrawal of the art rejections leaves the provisional rejection, which applicants say should be withdrawn according to MPEP 804 (1)(B).

10. Applicants' arguments filed 09/20/05 have been fully considered but they are not persuasive. The pending claims are rejected over prior art. According to MPEP 804 (1)(B), The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the

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applications. In this case, the provisional double patenting rejection is not the only rejection remaining in this application.

No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

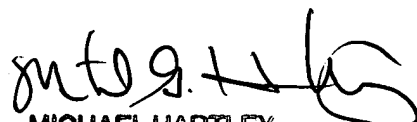
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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